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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,976	10/02/2000	Michael E. Kafrissen	ORT-1316	7964

7590

05/21/2002

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EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/677,976

Applicant(s)

KAFRISSEN ET AL.

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 21-23 are pending in the instant application. Acknowledgement is made of Applicant's amendment submitted 2/26/02.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mortimer (GB 2,131,292), further in view of Tepic et al. (U.S. Pat. No. 5,851,985).

Mortimer teaches progestational pharmaceutical formulations. Progestational Agents are known to cause desquamation of superficial cells of the vaginal mucosa, inhibit ferning of the cervical mucus, and induce withdrawal bleeds in oestrogen primed women (page 1, line 57-58). Mortimer teaches that patients for whom progestational agent therapy is appropriate would benefit from treatment with folic acid. Thus, Mortimer's invention provides a pharmaceutical formulation providing a progestationally active agent and folic acid (page 1, lines 62-63). A suitable dose rate for folic acid would be 2.5 to 20 mg (Id. at line 64). Norgestrel and Norethisterone are listed as suitable compounds for use in Mortimer's invention (page 19 and 20).

Tepic teaches that HeLa cells (human cervical carcinoma), after treatment of Tepic's composition, were dead in 96 hours. Tepic's composition (concentration) contains folic acid and d-biotin (col. 15, line 11-13).

Motivation to use folic acid in combination with a progestational compound is evident from the teaching of Mortimer. Whereas Mortimer does not term his progestational compounds "oral contraceptives", the progestational compounds are the same as those listed in the instant application, and thus makes obvious the use of "oral contraceptives" in the instant application. Further motivation to use folic acid with progestational compounds would have arisen because it is taught that folic acid has beneficial effects, including being used to kill cervical carcinoma cells.

### ***Response to Arguments***

2. Applicant's arguments filed 2/26/02 have been fully considered but they are not persuasive.

Applicant asserts that Mortimer does not a pharmaceutical preparation that comprises both an oral contraceptive and folic acid. However, Mortimer clearly teaches the use of Norgestrel and Norethisterone. Whereas he does not term these "oral contraceptives", they correspond to the compounds taught in the instant invention.

Applicant also asserts that Tepic does not teach folic acid being effective in killing cervical carcinoma cells, nor a combination of folic acid and an oral contraceptive. Tepic has as the goal the deprivation of arginine from tumor cells to manipulate proliferation of the cells (drive the level of proliferation down) (col. 3, lines 10-48). In in-vitro analysis, it was shown that HeLa (human cervical carcinoma) cells were dead after 96 hours of arginine deprivation (col. 7, lines 45-57). Tepic teaches using a concentration in animal experiments to affect the deprivation of arginine (col. 9, lines 49-

53). The concentration used in the animal experiments to deprive arginine and thus affect cell proliferation, prepared at column 14, line 54-column 15, line 32, specifically contained folic acid and d-biotin (col. 15, lines 11-13).

Thus, the rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

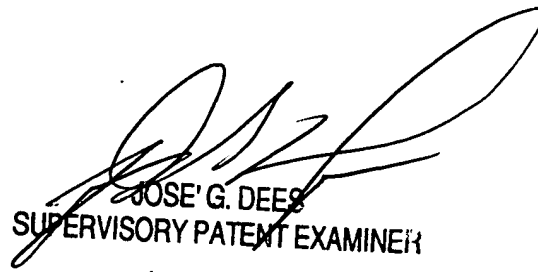
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD

May 9, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
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